April 3, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The International Banana Association (IBA) is providing these comments to the February 3, 2003 Federal Register notice (Vol. 68, No. 22, pp. 5428-5468) on the proposed rule requiring prior notice of imported food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

IBA is the trade organization representing the common business interests of the banana industry. IBA members are companies involved in the growing, shipping and importation of bananas into the United States. These members include Banacol Marketing Corporation, Chiquita Fresh North America, Del Monte Fresh Produce Inc., Dole Food Company, Le Best Banana Supply, Pacific Fruit Inc., and Turbana Corporation. Altogether these companies are responsible for importing over 98% of the bananas consumed in the U.S.

Virtually all bananas consumed in the U.S. are imported from countries in Latin America. In 2002, the banana industry imported around 204 million boxes of bananas, or over 8 billion pounds of bananas. On a weekly basis, an average between 3.5 to 4 million boxes of bananas is imported into the U.S. The importation of bananas is not only a recurring event throughout the year, but it has a historical record of being a safe and reliable operation.

IBA members strongly support the goal of the Bioterrorism Act to strengthen the safety of our food supply and the efforts by the Food and Drug Administration (FDA) to implement rulemaking that is consistent with the intent of the law. IBA members have the highest commitment to food safety and their business operations are first-rate in ensuring the quality and security of their fresh products. IBA's comments serve to provide feedback to FDA on the implementation of the Bioterrorism Act in regards to the prior notice requirements for all imported food. The following six points summarize our comments for FDA's consideration, with an explanation of each point below:

- FDA's prior notice rule adds duplicative regulatory burdens on importers of food when other federal agencies have similar requirements;

727 North Washington Street, Alexandria, Virginia 22314 (703) 836-5499 Fax: (703) 836-2049 E-Mail: iba@uffva.org

- FDA's definition of "food" includes packaging materials that contact food. IBA seeks clarification from FDA that immediate food packaging is not subject to the prior notice requirements.

- In reporting product quantity with the prior notice, the amendment process 2 hours before arrival should be sufficient for importers of bananas to accurately provide quantity information. FDA should consider similar measures taken by the U.S. Customs Service in establishing a discrepancy tolerance for quantities of perishable commodities.

- The reporting of grower information would be difficult and burdensome on importers of bananas since the number of independent growers that supply bananas on a single shipment can be large. IBA requests FDA to consider providing flexibilities or other options in the requirement to report grower information with the prior notice.

- IBA supports FDA's backup plan for filing prior notices if it cannot be done electronically. However, FDA should make sure complete contact information is provided to importers for each FDA field office.

- FDA should be responsible for costs incurred as a result of mistakes made in the enforcement of the rule that results in the holding of imported food.

Duplicative Regulatory Oversight

In the proposed rule, FDA "seeks comment on the extent to which these proposed prior notice requirements would result in persons submitting duplicative prior notice information to more than one federal agency." IBA believes that the FDA proposed rule on prior notice is duplicative to the import requirements imposed by other federal agencies, namely the U.S. Customs Service and the U.S. Coast Guard.

On October 31, 2002 the U.S. Customs Service issued their final rule (24 Hour Rule) requiring the presentation of vessel cargo declaration to Customs 24 hours before the cargo is laden aboard the vessel at the foreign port. Many of the fourteen data elements required by Customs on the advance cargo manifest are similar to the data requirements outlined in FDA's proposed rule. Customs' 24 Hour Rule only applies to the importation of cargo in containers that are shipped by ocean vessels, as carriers of bulk and break bulk cargo can apply for an exemption. Companies that receive an exemption to the 24 Hour Rule must submit their cargo declaration information to Customs 24 hours prior to arrival in the U.S., if they are participants in the Automated Manifest System (AMS), or upon arrival if they are nonautomated carriers.

On February 28, 2003, the U.S. Coast Guard issued their final rules pertaining to the notification of arrival (NOA) at U.S. ports. Again, a complete disclosure of importer and cargo information is required by the Coast Guard. In this case the Coast Guard is requiring importers to file Customs' Cargo Declaration Form 1302 at least 24 hours

before arriving at the U.S. port., and 96 hours prior to arrival for vessels on longer voyages.

FDA's rule to receive prior notice information adds another layer of regulatory burden on importers when most of the information required by FDA is already filed with the U.S. government to meet Customs and Coast Guard requirements, usually well before FDA's filing deadline of "noon the day before arrival." FDA should learn from the Coast Guard's actions and use the data already transmitted to Customs through AMS. Importers should only have to file once with the U.S. government; federal agencies should be able to better cooperate on these import rules.

IBA recognizes FDA's efforts to arrange for the filing of prior notice through Customs' new Automated Commercial Environment (ACE). IBA encourages the U.S. government to more rapidly develop and implement ACE to alleviate duplicative regulatory oversight on importers of food.

§1.277 (c)(3) Definition of "Food"

FDA defines food in this proposed rule to include "substances that migrate into food from food packaging and other articles that contact food." In previous interpretations of this statement, namely from the proposed §1.227(c)(4) of the food facility registration rule, FDA clarifies that "'Substances that migrate into food from food packaging' include immediate food packaging or components of immediate food packaging that are intended for food use."

Does this mean that the import of food contact packaging materials along with the food article, such as plastic lining inside a carton, must also be subject to the prior notice filing requirements? If, by FDA's definition, packaging that contacts food is defined as food under the rule, then it seems that the import of food packaging would require a prior notice in addition to the actual food article.

IBA questions this interpretation for the prior notice rule. Clearly the intent of the prior notice rule is for FDA to receive advance import notice of food articles, not immediate food packaging. IBA believes that clarification is needed in the rule given FDA's use of a broad definition for "food" that includes packaging materials. FDA should clarify that prior notice is not required for immediate food packaging, just the food article.

§1.288(e)(iv) Quantity of Food

FDA is proposing to require "the submission of the quantity of food described from smallest package size to largest container as an element of the identity of the product." In the proposed rule, FDA "requests comment on whether changes in quantity will occur after the deadline for prior notice and, if so, how commonly changes occur and how significant the changes usually are."

The tallying and reporting of piece count and weight can be an inexact exercise for many fresh produce commodities, including bananas. This requirement is a primary concern that has been expressed to the U.S. Customs Service in response to Customs' implementation of the 24 Hour Rule. To optimize freshness and quality, many agricultural products are harvested, packaged and loaded all right up to the time the ship leaves the foreign port. To meet Customs' new requirements for importing bananas in cargo containers, filers of advance manifests (24 hours prior to loading at foreign port) can only estimate the amount and weight of final packaging from harvests.

Experience to date regarding compliance to Customs' 24 Hour Rule indicates that a range in manifest reporting inaccuracy for product quantity can exist for perishable agricultural commodities from 6% to 15%. Different fresh products require more flexibility than others. For example, bananas, melons and pineapples have standard weight and box count in the container due to consistency in packaging (i.e. bananas are always packed in 40 pound boxes). For these commodities, greater accuracy in reporting can be achieved. In contrast, commodities such as grapes, apples, cherries and kiwis are packaged in different box sizes. Therefore, more variations from the initial forecasts in box and weight count can be expected for these commodities.

Customs has recognized the uniqueness and difficulty of reporting in advance packaging quantities of perishable merchandise, and has allowed for a "discrepancy tolerance" of 3% for perishable products (refer to Customs' 24 Hour Rule FAQ document, Item 23). If actual product quantity is within this tolerance range, then no amendment to the manifest is required by Customs.

IBA recognizes that the time of FDA's prior notice, being noon the day before arrival, is later in the transportation cycle than Customs' requirement of the data 24 hours in advance of loading at the foreign port. Therefore, FDA's prior notice rule would provide an importer with more time to accurately calculate and report product quantity. In addition, the inclusion of product quantity as a data element that can be amended up to 2 hours prior to arrival gives an importer the needed flexibility to accurately report product quantity.

IBA believes that the deadline for prior notice is adequate for the reporting of product quantity information for most shipments of bananas. But the amendment process is an important option for importers of bananas, which will improve the accuracy of the prior notice. IBA anticipates that the amendment process will be used frequently, especially for shipments of bananas from ocean vessels that travel shorter distances from Latin America to the U.S.

Taking into account the variations that may occur in the calculation of product quantity, even up until 2 hours prior to arrival at the U.S. port, FDA should consider allowing a similar discrepancy tolerance for perishable merchandise like the U.S. Customs Service. This may become more necessary for importers of fresh food using trucks to carry product over land border crossings, a transportation mode that often gives less lead time for reporting as when carrying product by ocean vessel.

§1.288(g) Grower Information

IBA is most concerned over the requirement to report "the identity of all growers of each article and the growing location if different from the grower's business address." FDA emphasizes in the proposed rule that "if a product is sourced from more than one grower, the prior notice must provide the identification of all growers, if known."

This requirement is very troublesome for the banana industry. Compliance to this portion of the rule could place great burden on importers of bananas. For example, in Ecuador there are over 5,000 small, independently-owned banana farms. Ecuador supplies approximately 25% of the bananas imported into the U.S. Ships leave from Ecuador carrying bananas to the U.S. every week, and the bananas aboard a single ship may come from hundreds of different farms. The reporting of hundreds of growers and their unique locations on every prior notice would be a very complex and time-consuming activity, if not an impossible task.

Also, FDA suggests that the Prior Notice System "will be developed to accommodate submission of up to three different growers." Clearly this subpart of the rule has not been developed to accommodate the unique and widespread farming operations like the banana industry.

IBA requests FDA to consider an option related to this requirement, which would alleviate the problems associated with compliance to the frequent reporting of excessive grower information. The proposed option is as follows:

In lieu of listing all growers each time of import, the rule could provide an alternative to filers of the prior notice to submit a one-time listing of all growers that supply the importing firm with product. Then the responsible party could update that list with FDA as changes in the product suppliers occur. This flexibility is a reasonable approach for importers that make regular and consistent imports of the same product from a consistent supply source. Bananas are imported weekly throughout the year by the same small number of companies from generally the same domain of suppliers.

It is puzzling why the U.S. Congress would exempt farms in the food facility registration provision of the Act, which would record farm/grower information through a one-time registration process, but then mandates FDA to repeatedly collect the same information – in a manner much more burdensome to the industry – through the prior notice process.

IBA believes that providing the industry with an option to submit the grower information one time to cover subsequent prior notices would reduce the redundant burdens that this requirement would cause importers of bananas, while having a negligible impact on the intent of the rule for FDA to screen the safety risks of all imported foods.

§1.287 (b) Inactive Prior Notice System

IBA agrees with FDA's backup plan for filing prior notices if the Prior Notice System is unable to receive a prior notice electronically. The delivery of a prior notice to the applicable FDA field office using E-mail, Fax or via in person is a reasonable option.

IBA requests that full contact information of all FDA field offices is made available, including the names and telephone numbers of FDA officials whom can assist an importer in filing a complete and accurate prior notice should questions or an urgent matter arise.

§1.278 (d) Failing to Submit Adequate Prior Notice: Responsibility of Expenses

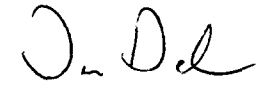
This section of the proposed rule requires that "transportation and storage expenses shall be borne by the owner, purchaser, importer, or consignee" if FDA determines that an imported article of food must be held at the port or removed to another storage location.

The holding of perishable food commodities can be detrimental to the quality and value of the product. The consequences of food products being held as a result of non-compliance to the rule can be costly, but IBA agrees that in such cases of non-compliance it is the responsibility of the private parties to cover all costs incurred in the transportation and storage of those products.

However, if by some rare occurrence FDA is imperfect in the enforcement of the rule and mistakenly holds imported product because of an oversight in the government's records of a prior notice, then FDA should be accountable to such errors and assume the responsibility of not only the transportation and storage fees but also any lost value as a result of damage to the quality of the food product.

Thank you for the opportunity to participate in the rulemaking process by presenting the above comments. Please contact me at (540) 314-3214 if you have any questions or wish to discuss these comments in further detail.

Sincerely,



Tim Debus
Executive Director